IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PF PRISM C.V., PBG PUERTO RICO LLC, and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MSN LABORATORIES PRIVATE LTD.,	)	
Defendant.	)	

COMPLAINT

Pfizer Inc., C.P. Pharmaceuticals International C.V., PF PRISM C.V., PBG Puerto Rico LLC, and PF PRISM IMB B.V. (collectively, "Pfizer" or "Plaintiffs") for their Complaint against MSN Laboratories Private Ltd. ("MSN") allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against MSN for infringement of United States Reissue Patent No. RE41,783 ("the RE'783 patent").

2. This action arises out of MSN's filing of Abbreviated New Drug Applications ("ANDAs") Nos. 217299 and 217298, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of, respectively, Pfizer's Xeljanz® (tofacitinib) 5 mg and 10 mg tablets and Pfizer's Xeljanz® Oral Solution (tofacitinib), 1 mg/mL, prior to the expiration of the RE'783 patent. MSN's ANDA products are referred to hereinafter as, respectively, "MSN 5 mg and 10 mg Generic Tablets" and "MSN Generic Oral Solution," and collectively, as "the MSN Generic Products."

THE PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

4. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having a place of business at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

6. Plaintiff PBG Puerto Rico LLC is a limited liability company organized and existing under the laws of Puerto Rico and having its principal place of business at Professional Offices Park V, 996 San Roberto Street, 4th Floor, San Juan, Puerto Rico 00926. Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

7. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands. Pfizer Inc. is the ultimate parent company of PF PRISM IMB B.V.

8. On information and belief, defendant MSN is a company organized and existing under the laws of India, having its principal place of business at MSN House, No. C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, India.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a).

10. This Court has personal jurisdiction over MSN.

11. This Court has personal jurisdiction over MSN by virtue of the fact that, *inter alia*, MSN has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in the State of Delaware. In particular, this suit arises out of MSN's filing of ANDA Nos. 217299 and 217298, seeking FDA approval to sell MSN Generic Products prior to the expiration of the RE'783 patent throughout the United States, including in the State of Delaware.

12. On information and belief, if ANDA Nos. 217299 and 217298 are approved, the MSN Generic Products will, among other things, be marketed and distributed by MSN in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

13. MSN's infringing activities in filing ANDA Nos. 217299 and 217298 and its intent to commercialize and sell the MSN Generic Products have led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

14. In the alternative, this Court has personal jurisdiction over MSN under Federal Rule of Civil Procedure 4(k)(2). MSN has contacts with the United States by virtue, *inter alia*, of its filing ANDA Nos. 217299 and 217298 with the FDA.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391. As a foreign corporation, MSN may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

BACKGROUND

Xeljanz Tablets and Xeljanz Oral Solution

16. The active ingredient in Pfizer's Xeljanz products is tofacitinib citrate. Xeljanz tablets contain tofacitinib citrate in an amount equivalent to 5 mg and 10 mg of tofacitinib base in tablets formulated for twice-daily administration. Xeljanz Oral Solution contains tofacitinib citrate in an amount equivalent to 1 mg of tofacitinib base per 1 mL of solution formulated for twice-daily administration.

17. The FDA-approved Prescribing Information for Xeljanz states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo [2,3-d] pyrimidin-4-ylamino)-ß-oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

18. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or who are intolerant to TNF blockers; for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or who are intolerant to TNF blockers; for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or who are intolerant to TNF blockers; for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or who are intolerant to TNF blockers; and for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or who are intolerant to TNF blockers.

Orange Book Listings for Xeljanz Tablets and Xeljanz Oral Solution

19. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 and EQ 10 mg base tofacitinib citrate tablets, and Pfizer, Inc. holds approved NDA No. 213082 for EQ 1 mg/mL base tofacitinib citrate oral solution. Pfizer sells both products under the registered name Xeljanz.

20. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the RE'783 patent is listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz NDAs. The Orange Book listing for Xeljanz 5 mg and 10 mg tablets also lists U.S Patent No. 6,965,027, expiring March 25, 2023. MSN's ANDA notice letter re: Pfizer's Xeljanz (tofacitinib) 5 mg and 10 mg tablets does not reference a certification against the '027 patent.

21. The Orange Book lists the expiration date for the RE'783 patent as December 8, 2025.

The RE'783 Patent

22. On September 28, 2010, the United States Patent and Trademark Office ("USPTO") issued the RE'783 patent, titled "Pyrrolo[2,3-d]pyrimidine Compounds." The RE'783 patent is a reissue of U.S. Patent No. 6,627,754, which issued on September 30, 2003. The RE'783 patent is duly and legally assigned to Pfizer Inc. A copy of the RE'783 patent is attached hereto as Exhibit A.

23. On December 14, 2016, the USPTO issued a Notice of Final Determination extending the expiration date of the RE'783 patent to December 8, 2025.

24. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the RE'783 patent.

25. C.P. Pharmaceuticals International C.V. conveyed rights under the RE'783 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

26. Pfizer Pharmaceuticals LLC has conveyed its rights to the RE'783 patent to PBG Puerto Rico LLC.

27. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the RE'783 patent to PF PRISM IMB B.V.

MSN's Xeljanz Tablet ANDA

28. By letter re: "MSN's Notice of Paragraph IV Certification for U.S. Patent No. RE41,783 listed against Xeljanz® (tofacitinib citrate) 5 mg and 10 mg oral tablets," dated April 21, 2022 (the "MSN Tablet Notice Letter"), and received by Pfizer on April 25, 2022, MSN notified Pfizer that it had filed ANDA No. 217299 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell MSN 5 mg and 10 mg Generic Tablets—generic copies of Xeljanz (tofacitinib citrate EQ 5 mg and EQ 10 mg tablets)—prior to the expiration of the RE'783 patent. The MSN Tablet Notice Letter describes MSN 5 mg and 10 mg Generic Tablets as "tofacitinib citrate 5 mg and 10 mg oral tablets" containing the active ingredient "tofacitinib citrate."

29. The MSN Tablet Notice Letter states that ANDA No. 217299 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" MSN 5 mg and 10 mg Generic Tablets prior to the expiration of the RE'783 patent.

30. The MSN Tablet Notice Letter asserts that ANDA No. 217299 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the RE'783 patent "is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of [MSN 5 mg and 10 mg Generic Tablets]."

31. The MSN Tablet Notice Letter included a "detailed statement of the factual and legal basis for MSN's assertion that claims of the patent at issue are invalid, unenforceable or not infringed by the commercial manufacture, use, importation, offer or sale of [MSN 5 mg and 10 mg Generic Tablets]." ("MSN's Tablet Detailed Statement"). Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), MSN's Tablet Detailed Statement asserts the purported factual and legal bases for MSN's contention that the RE'783 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of MSN 5 mg and 10 mg Generic Tablets.

32. MSN's Tablet Detailed Statement alleges that all claims of the RE'783 patent are invalid, but does not allege that MSN 5 mg and 10 mg Generic Tablets do not infringe the RE'783 patent.

33. On information and belief, upon approval of ANDA No. 217299, MSN will sell and distribute MSN 5 mg and 10 mg Generic Tablets throughout the United States.

MSN's Xeljanz Oral Solution ANDA

34. By letter re: "MSN's Notice of Paragraph IV Certification for U.S. Patent No. RE41,783 listed against Xeljanz® (tofacitinib citrate) 1 mg/ml base oral solution," dated May 11, 2022 (the "MSN Oral Solution Notice Letter") and received by Pfizer on May 12, 2022, MSN notified Pfizer that it had filed ANDA No. 217298 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell MSN Generic Oral Solution—a generic version of Xeljanz Oral Solution (tofacitinib citrate EQ 1 mg/mL oral solution)—prior to the expiration of the RE'783 patent. The MSN Oral Solution Notice Letter describes MSN Generic Oral Solution as "tofacitinib citrate 1 mg/ml base oral solution" with the active ingredient of "tofacitinib citrate."

35. The MSN Oral Solution Notice Letter states that ANDA No. 217298 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" MSN Generic Oral Solution prior to the expiration of the RE'783 patent.

36. The MSN Oral Solution Notice Letter asserts that ANDA No. 217298 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the RE'783 patent "is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of [MSN Generic Oral Solution]."

37. The MSN Oral Solution Notice Letter included a "detailed statement of the factual and legal basis for MSN's assertion that claims of the patent at issue are invalid, unenforceable or not infringed by the commercial manufacture, use, importation, offer or sale of [MSN Generic Oral Solution]" ("MSN's Oral Solution Detailed Statement"). Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), MSN's Oral Solution Detailed Statement asserts the purported factual and legal bases for MSN's contention that the RE'783 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of MSN Generic Oral Solution.

38. MSN's Oral Solution Detailed Statement alleges that all claims of the RE'783 patent are invalid, but does not allege that MSN Generic Oral Solution does not infringe the RE'783 patent.

39. On information and belief, upon approval of ANDA No. 217298, MSN will sell and distribute MSN Generic Oral Solution throughout the United States.

COUNT I

(Infringement of the RE'783 Patent by MSN 5 mg and 10 mg Generic Tablets)

40. The allegations of paragraphs 1-39 above are repeated and re-alleged as if set forth fully herein.

41. Pursuant to 35 U.S.C. § 271(e)(2)(A), MSN's filing of ANDA No. 217299 seeking approval to market MSN 5 mg and 10 mg Generic Tablets was an act of infringement of at least claim 4 of the RE'783 patent, entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 217299 be a date which is not earlier than the expiration date of the RE'783 patent.

42. MSN had knowledge of the RE'783 patent when it submitted ANDA No. 217299 to the FDA.

43. MSN 5 mg and 10 mg Generic Tablets infringe at least claim 4 of the RE'783 patent.

44. On information and belief, upon FDA approval, MSN intends to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN 5 mg and 10 mg Generic Tablets and will thereby infringe at least claim 4 of the RE'783 patent.

45. The foregoing actions by MSN constitute and/or would constitute infringement of at least claim 4 of the RE'783 patent.

46. Pfizer will be substantially and irreparably harmed if MSN is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

COUNT II
(Infringement of the RE'783 Patent by MSN Generic Oral Solution)

47. The allegations of paragraphs 1-46 above are repeated and re-alleged as if set forth fully herein.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), MSN's filing of ANDA No. 217298 seeking approval to market MSN Generic Oral Solution was an act of infringement of at least claim 4 of the RE'783 patent, entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter*

alia, an order of this Court that the effective date of approval for ANDA No. 217298 be a date which is not earlier than the expiration date of the RE'783 patent.

49. MSN had knowledge of the RE'783 patent when it submitted ANDA No. 217298 to the FDA.

50. MSN Generic Oral Solution infringes at least claim 4 of the RE'783 patent.

51. On information and belief, upon FDA approval, MSN intends to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN Generic Oral Solution and will thereby infringe at least claim 4 of the RE'783 patent.

52. The foregoing actions by MSN constitute and/or would constitute infringement of at least claim 4 of the RE'783 patent.

53. Pfizer will be substantially and irreparably harmed if MSN is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that MSN's submission of ANDA No. 217299 was an act of infringement and that MSN's making, using, offering to sell, selling, or importing MSN 5 mg and 10 mg Generic Tablets prior to the expiration of the RE'783 patent will infringe the RE'783 patent;

B. A judgment that the effective date of any FDA approval for MSN to make, use, offer for sale, sell, market, distribute, or import MSN 5 mg and 10 mg Generic Tablets be no earlier than the date on which the RE'783 patent expires, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction enjoining MSN, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them,

from making, using, selling, offering for sale, marketing, distributing, or importing MSN 5 mg and 10 mg Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the RE'783 patent, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

D. A judgment that MSN's submission of ANDA No. 217298 was an act of infringement and that MSN's making, using, offering to sell, selling, or importing MSN Generic Oral Solution prior to the expiration of the RE'783 patent will infringe the RE'783 patent;

E. A judgment that the effective date of any FDA approval for MSN to make, use, offer for sale, sell, market, distribute, or import MSN Generic Oral Solution be no earlier than the date on which the RE'783 patent expires, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

F. A permanent injunction enjoining MSN, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering for sale, marketing, distributing, or importing MSN Generic Oral Solution, and from inducing or contributing to any of the foregoing, prior to the expiration of the RE'783 patent, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

G. A judgment that this is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

H. An award of Pfizer's costs and expenses in this action; and

I. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

Aaron Stiefel
Daniel P. DiNapoli
Michael Sapiro
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000

Soumitra Deka
DLA PIPER LLP (US)
555 Mission Street, Suite 2400
San Francisco, CA 94105-2933
(415) 836-2500

June 6, 2022